



PATENT
Docket No. 2629-4005US3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Attila T. LORINCZ, et al.

Group Art Unit: 1631

Serial No : 09/598,571

Examiner: Siu, S.

Filed : June 21, 2000

For : **UNIVERSAL COLLECTION MEDIUM**

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner of Patents
Washington, D.C. 20231

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Sir:

This is a Declaration under 37 C.F.R. §1.132 by Dr. Attila T. Lorincz in the above-identified application.

I, the undersigned, Attila T. Lorincz, Ph.D., declare and state that:

1. My education and professional experience as an expert in the area of nucleic acid chemistry and analysis are set forth on the attached copy of my Curriculum Vitae (Exhibit A).
2. As stated on my Curriculum Vitae, my area of expert training and experience is in nucleic acid chemistry, in the analysis of nucleic acids in biological samples, and in the use of such nucleic acid analyses to develop diagnoses and prognoses concerning diseases related to the organism from which the nucleic acid was obtained.
3. I have read and understand the Office Action dated November 14, 2000, issued in the above-identified application. I have read and understand the above-identified

patent application and the pending claims.

4. I understand that the Examiner considers the composition reported at column 3, lines 55-67; column 4, lines 16-18; and in Example 2 of Dunphy U.S. Patent No. 5,679,333 to anticipate and/or make obvious the composition described in claims 1-13, 16-19, and 21 of the above-identified application.
5. It is my opinion, as an expert in the field of nucleic acid chemistry and analysis, that the composition described in Dunphy does not anticipate the composition described in claims 1-13, 16-19, and 21 of the above-identified application because the composition of Dunphy does not make possible the direct analysis of cells contained in the composition by both cytological analysis and molecular analysis of DNA, RNA, or protein.
6. Evidence establishing that the Dunphy composition does not make possible the direct analysis of cells according to the subject claims is provided by the following experimental results using the Dunphy composition to analyze cellular DNA and RNA.
7. The preferred solution described in Dunphy Example 2 was prepared as follows and used in the molecular analyses described below:

| | |
|-------------------------------|-------------|
| Ethanedial | 28.0% v/v |
| Ethanol | 15.0% v/v |
| Polyethylene Glycol (MW 8000) | 2.5% w/v |
| Ethylene Glycol | 0.3% v/v |
| Ethanoic Acid | 0.5% v/v |
| 1-Hexadecylpyridinium | 0.06% w/v |
| Chloride | |
| Dimethyl Sulfoxide | 0.0275% v/v |
| EDTA | 0.08% w/v |
| Water | 53.5% v/v |

8. The following composition described in the subject application ("UCM") was prepared as follows and used in the molecular analyses described below:

| | |
|---------------|-----------|
| Butanol | 9% v/v |
| PEG (MW 1450) | 2% w/v |
| Sodium Azide | 0.05% w/v |

| | |
|----------------------------|-------|
| EDTA | 5 mM |
| Sodium Acetate-Acetic Acid | 10 mM |
| pH | 4.5 |

9. Cultured, HPV 16-positive CaSki cells and HPV-negative Jurkat cells were used to examine whether or not the Dunphy composition makes possible the direct analysis of nucleic acid.
10. The Dunphy composition and the UCM composition were spiked with Jurkat cells and three different concentrations of CaSki cells. The HPV-negative Jurkat cell samples were used to determine the background noise. The spiked samples were then stored at room temperature and examined within 24 hours. The spiked samples were further examined at about 48 hours and again at about 72 hours.
11. Cellular DNA was examined by directly testing the samples using the Hybrid Capture DNA assay from a standard Hybrid Capture II HPV Test Kit (Digene catalog number 5101-1069) according to the standard operation procedure provided with the kit. The test kit detects HPV DNA. The procedure for the nucleic acid assay is also described in WO 93/10263.
12. Table 1 shows the test data expressed as a S/N ratio average for the three measurements taken at approximately 24, 48, and 72 hours.
13. Table 1. Hybrid Capture II DNA assay signal to noise ratios.

| HPV(+) Cell concentration (cell/ml) | 0 | | 100 | | 1000 | | 10000 | |
|-------------------------------------|-----|--------|------|--------|------|--------|-------|--------|
| | S/N | St dev | S/N | St dev | S/N | St dev | S/N | St dev |
| UCM composition | 1 | 0 | 7.6 | 0.75 | 68.3 | 3.06 | 665 | 16.09 |
| Dunphy composition | 1 | 0 | 0.96 | 0.11 | 1.03 | 0.07 | 1.02 | 0.12 |

14. Table 1 shows that at zero concentration of cells the signal to noise ratio (S/N) was 1, i.e. there was no signal, for both the Dunphy and UCM compositions. The table shows that the UCM composition produced a signal to noise ratio of 7.6 when there were 100 cells per milliliter, while the Dunphy composition produced

no signal, i.e. a signal to noise ratio of 1, at this concentration. The UCM composition produced a signal to noise ratio of 68.3 when there were 1000 cells per milliliter and a signal to noise ratio of 665 when there were 10,000 cells per milliliter, while the Dunphy composition produced no signal at these concentrations.

15. Table 1 shows that the Dunphy composition does not make the detection of a DNA signal that is distinguishable from the background possible at any of the cellular concentrations examined. On the other hand, the UCM composition does make possible the detection of a DNA signal, even at cellular concentrations as low as 100 cells per milliliter.
16. Similarly, RNA analysis of the samples was performed following the general principles of the Hybrid Capture method described in WO 93/10263. Briefly, the cellular RNA was released by digesting the sample with proteinase, and then biotinylated single-stranded DNA probes specific for HPV 16 E6/E7 RNA added. Following hybridization, the sample was transferred to a streptavidin-coated microplate and anti-hybrid antibody added. Detection was performed as described in WO 93/10263.

17. Table 2. Hybrid Capture II RNA assay signal to noise ratios.

| HPV(+) Cell concentration (cell/ml) | 0 | | 100 | | 1000 | | 10000 | |
|-------------------------------------|-----|--------|------|--------|------|--------|-------|--------|
| | S/N | St dev | S/N | St dev | S/N | St dev | S/N | St dev |
| UCM composition | 1 | 0 | 2.4 | 0.26 | 16.6 | 0.83 | 147 | 7.02 |
| Dunphy composition | 1 | 0 | 0.95 | 0.08 | 0.99 | 0.16 | 1.04 | 0.16 |

18. Table 2 shows that at zero concentration of cells the signal to noise ratio (S/N) was 1, i.e. there was no signal, for both the Dunphy and UCM compositions. The table shows that the UCM composition produced a signal to noise ratio of 2.4 when there were 100 cells per milliliter, while the Dunphy composition produced

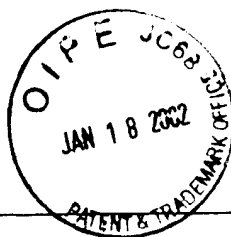
no signal, i.e. a signal to noise ratio of 1, at this concentration. The UCM composition produced a signal to noise ratio of 16.6 when there were 1000 cells per milliliter and a signal to noise ratio of 147 when there were 10,000 cells per milliliter, while the Dunphy composition produced no signal at these concentrations.

19. Table 2 shows that the Dunphy composition does not make the detection of an RNA signal that is distinguishable from the background possible at any of the cell concentrations examined. On the other hand, the UCM composition does make possible the detection of a RNA signal, even at cellular concentrations as low as 100 cells per milliliter.
20. The results shown in Tables 1 and 2 demonstrate that while the UCM composition makes possible the direct analysis of both RNA and DNA, the Dunphy composition fails to make possible a signal that is distinguishable from the background. In other words, the direct analysis of RNA and DNA using the Dunphy composition produces no meaningful result. Thus, the Dunphy composition does not make possible the direct analysis of cells contained in the composition by both cytological methods and molecular methods.
21. I declare further that all statements made on information and belief are believed to be true, and, further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the instant patent specification or any patent issuing thereon.

Respectfully submitted,

Date: March 8, 2001

Atila T. Lorincz
Atila T. Lorincz, Ph.D.



Curriculum Vitae

ATTILA T. LÖRINCZ, Ph.D.

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Work: Digene Corporation
1201 Clopper Road
Gaithersburg, MD 20878
Phone: 301-944-7350
E-mail: ATTILA.LORINCZ@DIGENE.COM

Home: 6 Chinaberry Court
North Potomac, MD 20878
Phone: 301-869-2404

University Education:

Graduate, 1976-1979 Department of Genetics, Trinity College, Dublin, Ireland.
Ph.D., 1980. Research project: Investigation of cell size and cell division control in *Saccharomyces cerevisiae*.

Undergraduate, 1972-1976 University College, Dublin, Ireland.
B.Sc., Honors 1976. Microbiology (major), Biochemistry (minor).
Research project: Characterization of an α -amylase of *Pseudomonas saccharophila*.

Professional Positions:

Senior Vice President and Chief Scientific Officer, since 2000. Digene Corporation, Gaithersburg, Maryland 20878.

Report directly to company President and CEO. Responsibilities include: key role in company policy decision-making at the executive committee level; speaking at scientific meetings worldwide as an acknowledged expert on human papillomaviruses and genetic testing; instigating and supervising basic scientific research; collaborating with scientists worldwide in studies published in prestigious peer-reviewed journals; evaluating Digene's position on intellectual property; evaluating new technology in other laboratories for possible licensing or other use by Digene; representing Digene and its technology at business meetings worldwide.

Vice President, R&D, and Scientific Director, 1990-1999.

Responsibilities included: supervision and guidance of up to 40 scientists, long-range scientific planning for the company, review of detailed research plans, assurance of quality results, and timely achievement of company R&D goals. Principal areas of research focus were the development of diagnostic nucleic acid probe tests for a broad range of human infectious diseases, cancers, and inherited disorders. Other responsibilities included the planning and coordination of clinical studies, U.S. Food and Drug Administration submissions, and interactions with high-level biomedical consultants and collaborators from universities and other companies.

Lecturer, 1999. Zanvyl Krieger School of Arts and Sciences, Johns Hopkins University, Montgomery County Center, Rockville, MD 20850.

Designed and taught a new course in the history of medical diagnostics for candidates for the M.A. in Biotechnology.

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Adjunct Associate Professor, 1989-present. Department of Pathology, Georgetown University Medical School, Washington, DC 20007.

Research efforts focused on human papillomaviruses, with particular emphasis on diagnostic applications, and on molecular mechanisms of carcinogenesis in human keratinocytes. Other projects involved the study of tumor suppressor genes and their use as markers for cancer prognosis.

Scientific Director, Corporate Research, 1989-1990. Life Technologies, Inc., Gaithersburg, Maryland. Studied *in vitro* transcription, transgenic animals, and other model systems of interest to research scientists for the purpose of generating research reagents.

Section Head of Advanced Molecular Diagnostics, 1984-1989. Life Technologies, Inc. Gaithersburg, Maryland. Investigated medical and molecular aspects of the human papillomavirus.

Research Scientist, 1982-1984. University of California at Santa Barbara. Investigated regulation and organization of *S. cerevisiae* genes involved in cell cycle control.

Research Scientist, 1980-1982. University of California at San Diego. Performed quantitative computer analyses of protein regulation during the cell cycle of *S. cerevisiae*, using two-dimensional gel electrophoresis.

Honors And Other Professional Activities:

High Technology Council of Maryland Award for Biotechnology Product of the Year 2000, awarded to the Hybrid Capture® II HPV DNA Test.

American Venereal Disease Association A.V.D.A. Achievement Award 1994, presented in recognition of outstanding contributions toward the control of sexually transmitted diseases.

Primary author of cell cycle paper in *Nature*, 1984.

Senior author of papers in *JAMA*, 2000, detailing the role of HPV in cervical cancer screening.

Editorial board member of *IVD Technology* and of *Clinical and Diagnostic Virology*.

Scientific and medical reviewer for: *Obstetrics and Gynecology*, *Science*, *Journal of Clinical Microbiology*, *Journal of General Virology*, *Clinical and Diagnostic Virology*, and others.

Peer reviewer for the National Institutes of Health, since 1986.

Life Technologies, Inc., David L. Coffin Award for Technical Innovation, for developing the FDA approved HPV test ViraPap®, 1989.

Life Technologies, Inc., David L. Coffin Patent Award, for human papillomavirus 56 nucleic acid hybridization probes and methods for employing same, US Patent No. 4,908,306.

Irish Department of Education Ph.D. Scholarship Recipient, 1976-1979.

National Clinical Trials:

Co-principal investigator for HPV QC Group in the NCI ALTS study to investigate alternatives in women's health care for managing cervical disease. Contract NCI-CN-55044-07, awarded 1995.

ER09898160545

Federal Research Grants:

Principal Investigator for Contract N44-AI-85335, "Rapid Detection and Typing of HSV DNA." SBIR Phase II grant from NIAID, awarded May, 1998.

Principal Investigator for Contract N43-AI-45214, "Rapid Detection and Typing of Herpes Simplex virus (HSV) DNA in Clinical Specimens." SBIR Phase I grant from NIAID, completed 1996.

Subcontract MA-5623-26 with Microbiological Associates, Inc., "Assays to Detect and Type Human Papillomavirus DNA in Cervical Lavage Samples." Completed 1995.

Patents:

US patent nos. 4,849,331; 4,849,332; 4,849,334; and 4,908,306 for the use of HPV types 35, 43, 44, and 56 in diagnostic testing.

US patent nos. 5,981,179 and 6,027,897 and Australian patent no. 711130 for CAR target amplification technology.

Australian patent no. 673813 for Hybrid Capture[®] technology.

Other patents pending for Hybrid Capture[®] technology.

Memberships:

American Society for Microbiology (since 1980)

Pan American Group for Rapid Viral Diagnosis (since 1986)

American Association of Clinical Chemistry (since 1991)

International Committee on HPV Nomenclature (1986-1991)

International Conferences

Dr. Lőrincz has been an invited speaker at many international conferences, a list of which is available on request.

Departmental Seminars

Dr. Lőrincz has been an invited speaker at many departmental seminars, a list of which is available on request.

Managerial Experience:

- Head of several scientific teams, with full responsibilities for project planning, budgets, hiring, promotions, data analyses, presentations, publications, etc. Principal investigator for numerous clinical studies. As a member of the executive staff of Digene, I am intimately involved in setting overall company objectives and policies.
- Head of several multi-disciplinary strategic planning teams involving R&D, Regulatory Affairs, Marketing and Sales, Development, and Manufacturing.
- Director of Intellectual Property for Digene Corporation, 1990-1994. Prepared patent applications with assistance of attorneys.

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- Played a major role in preparing several PMA applications for Life Technologies' and Digene's HPV testing kits. Presented data to FDA panels, leading to successful approval of the ViraType® and Hybrid Capture® kits for detecting and typing HPV DNA.
- Key member of the Executive Committee directing a successful initial public offering of Digene Corporation on NASDAQ in May, 1996, and a secondary offering in October, 1997.

SELECTED PUBLICATIONS

Dr. Lörincz has 72 peer-reviewed scientific publications prior to 1995, a list of which is available on request. A list of peer-reviewed publication since 1995 follows:

Schiffman, M.H., N.B. Kiviat, R.D. Burk, K.V. Shah, R.W. Daniel, R. Lewis, J. Kuypers, M.M. Manos, D.R. Scott, M.E. Sherman, R.J. Kurman, M.H. Stoler, A.G. Glass, B.B. Rush, I. Mielzynska, and **A.T. Lörincz** (1995) Accuracy and interlaboratory reliability of human papillomavirus DNA testing by Hybrid Capture. *J. Clin. Microbiol.* 33:545-550.

Cox, J.T., **A.T. Lörincz**, M.H. Schiffman, M.E. Sherman, A. Cullen, and R.J. Kurman (1995) Human papillomavirus testing by hybrid capture appears to be useful in triaging women with a cytologic diagnosis of atypical squamous cells of undetermined significance. *Am. J. Obstet. Gynecol.* 172(3):946-954.

Reid, R., and **A.T. Lörincz** (1995) Human papillomavirus tests. In: *Ballière's Clinical Obstetrics and Gynaecology* (H.W. Jones, III, guest ed.), vol. 9, no. 1, pp. 63-103. Ballière Tindall, London.

Lörincz, A. (1995) Hybrid Capture™: A simple, sensitive method for the routine detection of HPV DNA. In: *Screening of Cervical Cancer: For Whom, Why and How? Experts' Conference. 2nd International Congress of Papillomavirus in Human Pathology.* Paris, France, Unesco, April 6, 7, 8, 1994 (Monsonago, J., ed.), pp. 59-62. EUROGIN Scientific Publications, Paris.

Wideroff, L.; Schiffman, M.H.; Nonnenmacher, B.; Hubbert, N.; Kimbauer, R.; Greer, C.E.; Lowy, D.; **Lörincz, A.T.**; Manos, M.M.; Glass, A.G.; Scott, D.R.; Sherman, M.E.; Kurman, R.J.; Buckland, J.; Tarone, R.E.; Schiller, J (1995) Evaluation of seroreactivity to human papillomavirus type 16 virus-like particles in an incident case-control study of cervical neoplasia. *J. Infect. Dis.* 172(6):1425-1430.

Lörincz, A. (1995) Human papillomaviruses. In: *Diagnostic Procedures for Viral, Rickettsial, and Chlamydial Infections*, 7th edition (Lennette, E.H., et al., eds.), pp. 465-480. American Public Health Association, Washington, D.C.

Lörincz, A. (1996) Hybrid Capture™ method for detection of human papillomavirus DNA in clinical specimens. *Papillomavirus Report* 7(1):1-7.

Reid, R.; **Lörincz, A.** (1996) New generation of human papillomavirus tests. In: *Cervical Cancer and Preinvasive Neoplasia* (Rubin, S.C.; Hoskins, W.J., eds.), pp. 27-47. Lippincott-Raven, Philadelphia.

Lörincz, A.T. (1996) Molecular methods for the detection of human papillomavirus infection. In: *Obstetrics and Gynecology Clinics of North America: The Papillomaviruses*, 2nd edition (Lörincz, A.T.; Reid, R., eds.), vol. 23, no. 3, pp. 707-730. W.B. Saunders, Philadelphia.

Tsukui, T.; Hildesheim, A.; Schiffman, M.H.; Lucci, J., III; Contois, D.; Lawler, P.; Rush, B.B.; **Lörincz, A.T.**; Corrigan, A.; Burk, R.D.; Qu, W.; Marshall, M.A.; Mann, D.; Carrington, M.; Clerici, M.; Shearer, G.M.; Carbone, D.P.; Scott, D.R.; Houghten, R.A.; Berzofsky, J.A. (1996) Interleukin 2 production *in vitro* by peripheral lymphocytes in response to human papillomavirus-derived peptides: correlation with cervical pathology. *Cancer Res.* 56(17):3967-3974.

Hall, S.; **Lörincz, A.**, Shah, F.; Sherman, M.E.; Abbas, F.; Paull, G.; Kurman, R.J.; Shah, K.V. (1996) Human papillomavirus DNA detection in cervical specimens by Hybrid Capture: correlation with cytologic and histologic diagnoses of squamous intraepithelial lesions of the cervix. *Gynecol. Oncol.* 62:353-359.

Wideroff, L.; Schiffman, M.H.; Hoover, R.; Tarone, R.E.; Nonnenmacher, B.; Hubbert, N.; Kimbauer, R.; Greer, C.E.; **Lörincz, A.T.**; Manos, M.M.; Glass, A.G.; Scott, D.R.; Sherman, M.E.; Buckland, J.; Lowy, D.; Schiller, J. (1996) Epidemiologic determinants of seroreactivity to human papillomavirus (HPV) type 16 virus-like particles in cervical HPV-16 DNA-positive and -negative women. *J. Infect. Dis.* 174(5):937-943.

Lörincz, A.T. (1996) Hybrid Capture™ method for detection of human papillomavirus DNA in clinical specimens: a tool for clinical management of equivocal Pap smears and for population screening. *J. Obstet. Gynaecol. Res.* 22(6):629-636.

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Sherman, M.E.; Schiffman, M.H.; **Lörincz, A.T.**; Herrero, R.; Hutchinson, M.; Bratti, C.; Zahniser, D.; Morales, J.; Hildesheim, A.; Helgesen, K.; Kelly, D.; Alfaro, M.; Mena, F.; Balmaceda, I.; Mango, L.; Greenberg, M. (1997) Cervical specimens collected in liquid buffer are suitable for both cytologic screening and ancillary human papillomavirus testing. *Cancer* 81(2):89-97.

Sherman, M.E.; Schiffman, M.H.; Mango, L.J.; Kelly, D.; Acosta, D.; Cason, Z.; Elgert, P.; Zaleski, S.; Scott, D.R.; Kurman, R.J.; Kiviat, N.B.; Stoler, M.; **Lorincz, A.T.** (1997) Evaluation of PAPNET testing as an ancillary tool to clarify the status of the "atypical" cervical smear. *Mod. Pathol.* 10(6):564-571.

Cope, J.U.; Hildesheim, A.; Schiffman, M.H.; Manos, M.M.; **Lörincz, A.T.**; Burk, R.D.; Glass, A.G.; Greer, C.; Buckland, J.; Helgesen, K.; Scott, D.R.; Sherman, M.E.; Kurman, R.J.; Liaw, K.-L. (1997) Comparison of the Hybrid Capture tube test and PCR for detection of human papillomavirus DNA in cervical specimens. *J. Clin. Microbiol.* 35(9):2262-2265.

Cullen, A.P.; Long, C.D.; **Lörincz, A.T.** (1997) Rapid detection and typing of herpes simplex virus DNA in clinical specimens by the Hybrid Capture II signal amplification probe test. *J. Clin. Microbiol.* 35(9):2275-2278.

Lörincz, A.T. (1997) Methods of DNA hybridization and their clinical applicability to human papillomavirus detection. In: *New Developments in Cervical Cancer Screening and Prevention* (Franco, E.; Monsonego, J., eds.), pp. 325-337. Blackwell Science, Oxford.

Herrero, R.; Schiffman, M.H.; Bratti, C.; Hildesheim, A.; Sherman, M.E.; Morales, J.; Mekbel, S.; Alfaro, M.; Balmaceda, I.; Greenberg, M.; **Lorincz, A.** (1997) Evaluation of multiple screening techniques in a high-risk area: the Guanacaste project. In: *New Developments in Cervical Cancer Screening and Prevention* (Franco, E.; Monsonego, J., eds.), pp. 389-399. Blackwell Science, Oxford.

Chesebro, M.J.; Everett, W.D.; **Lörincz, A.** (1997) High-risk human papillomavirus testing of women with cytological low-grade squamous intraepithelial lesions. *J. Lower Genital Tract Dis.* 1(4):234-239.

Hildesheim, A.; Schiffman, M.H.; Tsukui, T.; Swanson, C.A.; Lucci, J., III; Scott, D.R.; Glass, A.G.; Rush, B.B.; **Lorincz, A.T.**; Corrigan, A.; Burk, R.D.; Helgesen, K.; Houghten, R.A.; Sherman, M.E.; Kurman, R.J.; Berzofsky, J.A.; Kramer, T.R. (1997) Immune activation in cervical neoplasia: cross-sectional association between plasma soluble interleukin 2 receptor levels and disease. *Cancer Epidemiol. Biomarkers Prev.* 6(10):807-813.

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Ferris, D.G.; Wright, T.C., Jr.; Litaker, M.S.; Richart, R.M.; **Lorincz, A.T.**; Sun, X.-W.; Borgatta, L.; Buck, H.; Kramer, L.; Rubin, R. (1998) Triage of women with ASCUS and LSIL on Pap smear reports: management by repeat Pap smear, HPV DNA testing, or colposcopy? *J. Fam. Pract.* 46(2):125-134.

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Wright, T.C., Jr.; **Lorincz, A.**; Ferris, D.G.; Richart, R.M.; Ferenczy, A.; Mielzynska, I.; Borgatta, L. (1998) Reflex human papillomavirus DNA testing in women with abnormal Papanicolaou smears. *Am. J. Obstet Gynecol.* 178(5):962-966.

Lörincz, A. (1998) Hybrid Capture. *Clin. Chem.* 44(6):1363.

Nindl, I.; **Lörincz, A.**; Mielzynska, I.; Petry, U.; Baur, S.; Kirchmayr, R.; Michels, W.; Schneider, A. (1998) Human papillomavirus detection in cervical intraepithelial neoplasia by a second-generation hybrid capture microplate test, comparing two different cervical specimen collection methods. *Clin. Diagn. Virol.* 10:49-56.

Lörincz, A.; Davies, P.O. (1998) The Hybrid Capture II Assay for the detection of human papillomavirus. In: Genital Infections and Neoplasia Update. (Monsonogo, J., editor), pp 18-19. EUROGIN Scientific Publications, Paris.

Peyton, C.L.; Schiffman, M.; **Lörincz, A.T.**; Hunt, W.C.; Mielzynska, I.; Bratti, C.; Eaton, S.; Hildesheim, A.; Morera, L.A.; Rodriguez, A.C.; Herrero, R.; Sherman, M.E.; Wheeler, C.M. (1998) Comparison of PCR- and Hybrid Capture-based human papillomavirus detection systems using multiple cervical specimen collection strategies. *J. Clin. Microbiol.* 36(11):3248-3254.

Hildesheim, A.; Schiffman, M.; Scott, D.R.; Marti, D.; Kissner, T.; Sherman, M.E.; Glass, A.G.; Manos, M.M.; **Lorincz, A.T.**; Kurman, R.J.; Buckland, J.; Rush, B.B.; Carrington, M. (1998) Human leukocyte antigen class I/II alleles and development of human papillomavirus-related cervical neoplasia: results from a case-control study conducted in the United States. *Cancer Epidemiol. Biomarkers Prev.* 7:1035-1041.

Sherman, M.E.; Schiffman, M.; Herrero, R.; Kelly, D.; Bratti, C.; Mango, L.; Alfaro, M.; Hutchinson, M.L.; Mena, F.; Hildesheim, A.; Morales, J.; Greenberg, M.; Balmaceda, I.; **Lorincz, A.T.** (1998) Performance of a semiautomated Papanicolaou smear screening system: results of a population-based study conducted in Guanacaste, Costa Rica. *Cancer* 84(5):273-280.

Schneider, D.L.; Herrero, R.; Bratti, C.; Greenberg, M.D.; Hildesheim, A.; Sherman, M.E.; Morales, J.; Hutchinson, M.L.; Sedlacek, T.V.; **Lorincz, A.**; Mango, L.; Wacholder, S.; Alfaro, M.; Schiffman, M. (1999) Cervicography screening for cervical cancer among 8460 women in a high-risk population. *Am. J. Obstet. Gynecol.* 180(2):290-298.

Greenberg, M.D.; Reid, R.; Schiffman, M.; Campion, M.J.; Precop, S.L.; Berman, N.R.; Zemlo, T.; Husain, M.; Herman, G.; Omato, K.H.; **Lorincz, A.T.** (1999) A prospective study of biopsy-confirmed cervical intraepithelial neoplasia grade 1: colposcopic, cytologic, and virologic risk factors for progression. *J. Lower Gen. Tract Dis.* 3(2):104-110.

Girdner, J.L.; Cullen, A.P.; Salama, T.G.; He, L.; **Lorincz, A.**; Quinn, T.C. (1999) Evaluation of the Digene Hybrid Capture II CT-ID test for the detection of *Chlamydia trachomatis* in female endocervical specimens. *J. Clin. Microbiol.* 37(5):1579-1581.

Cox, J.T.; Herbst, A.L.; Kinney, W.; **Lörincz, A.T.**; Richart, R.M.; Schiffman, M.H. (1999) Advanced technologies in cervical cancer screening: ASCCP biennial meeting 1998. *J. Lower Gen. Tract Dis.* 3(suppl 1):S8-S28.

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Attachment A

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Attachment B

**INVITED SPEAKER
INTERNATIONAL CONFERENCES**

1. Bay Area Yeast Meeting. August 3, 1983. Berkeley, California.
2. Origin of Female Genital Cancer. April 14-17, 1985. Cold Spring Harbor, New York.
3. Workshop on Mechanisms of Transformation by Papillomaviruses. February 18-19, 1986. Bethesda, Maryland.
4. Colposcopy, Cervical and Vulvar Pathology and Gynecologic Laser Surgery Conference. April 4-10, 1986. Sarasota, Florida.
5. Human Papillomaviruses and Cervical Carcinoma. Second International Conference. October 27-29, 1986. Chicago, Illinois.
6. Human Papillomaviral Infection and Lower Genital Tract Neoplasia. May 7-9, 1987. Atlanta, Georgia.
7. HPV Workshop - Type Consensus Meeting. March 22-23, 1988. New York, New York.
8. Human Papillomaviruses and Squamous Carcinoma. Third International Conference. October 24-26, 1988. Chicago, Illinois.
9. Impact of HPV Testing on Cervical Cancer Screening and Diagnosis. National Cancer Institute Sponsored Conference. February 2, 1989. Rockville, Maryland.
10. Colposcopy, Cervical and Vulvar Pathology and Gynecologic Laser Surgery Conference. February 27-March 5, 1989. Sarasota, Florida.
11. UCLA Conference on Papillomaviruses. March 11-18, 1989. Taos, New Mexico.
12. An Update: Human Papillomavirus Infection. April 14, 1989. Lenexa, Kansas.
13. Fifth Annual Clinical Virology Symposium. April 30-May 3, 1989. Clearwater Beach, Florida.
14. Thirtieth Annual Meeting of the Japanese Clinical Cytology Society. June 14-16, 1989. Tokyo, Japan.
15. Colposcopy, Cervical and Vulvar Pathology and Gynecologic Laser Surgery Conference. November 5-12, 1989. Sarasota, Florida.
16. Human Papillomavirus Infections—A Postgraduate Course. October 21-22, 1989. Washington, DC.
17. Diagnosis and Treatment of Vulvar, Vaginal and Cervical Disease - A Postgraduate Course. October 27-28, 1989. Washington, DC.
18. National Meeting of the Canadian Association for Clinical Microbiology and Infectious Diseases. November 26-30, 1989. Montreal, Canada.
19. Workshop on Development of STD Diagnostics for Resource-Poor Settings. February 7-8, 1990. Rosslyn, Virginia.
20. Sixth Meeting of the Scandinavian Society for Gynecological Medicine. September 6-8th, 1990. Mariehamn, Finland.
21. International Symposium on Diagnosis of Sexually Transmitted Diseases. August 16-17, 1991. Uppsala, Sweden.
22. Fourth International Conference on Human Papillomaviruses and Genital Carcinoma. September 17-19, 1990. Chicago, Illinois.
23. Second IARC Workshop on HPV and Cervical Cancer, November 25-28, 1991. Brussels, Belgium.
24. Fifth International Conference on Human Papillomavirus. October 25-28, 1992. Chicago, Illinois.
25. St. Joseph's Institute of Laboratory Medicine Symposium. April 29, 1993. London, Ontario, Canada.
26. Twelfth Annual High Technology R&D Trade Fair. May 10-11, 1993. Arlington, Virginia.
27. 8th World Congress of Cervical Pathology and Colposcopy. May 12-16, 1993. Chicago, Illinois.
28. 1993 U.K. Wellcozyme Users Conference. June 17-18, 1993. St. Albans, England.

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29. Steering Committee Meeting of the International Biological Study on Cervical Cancer. October 2, 1993. Baltimore, Maryland.
30. The American Society for Colposcopy and Cervical Pathology, in joint sponsorship with The Society of Canadian Colposcopists. March 22-26, 1994. Orlando, Florida.
31. 2nd International Congress of Papillomavirus in Human Pathology. April 6-8, 1994. Paris, France.
32. Novel Amplification Technologies for DNA/RNA-Based Diagnostics. April 20-22, 1994. San Francisco, California.
33. First Congress on Papillomavirus of the Catholic Cancer Center. May 7, 1994. Seoul, Korea.
34. The Feasibility of Genetic Technology to Close the HIV Window in Donor Screening (US FDA workshop) September 26-28, 1994. Silver Spring, Maryland.
35. Nucleic Acid-Based Technology: Revolution in Clinical Diagnosis, Applications and Research. November 7-9, 1994. Amsterdam, The Netherlands.
36. Nucleic Acid-Based Technologies: Current Challenges, Future Strategies, and End User Perspectives. May 31-June 2, 1995. San Francisco, California.
37. Murex Users' Meeting. June 7-8, 1995. London, United Kingdom.
38. Eleventh Meeting of the International Society for STD Research, August 27-30, 1995. New Orleans, Louisiana.
39. X Congresso Brasileiro - II Congresso Latino Americano de Patologia do Trato Genital Inferior e Colposcopia. September 20-24, 1995. Sao Paulo, Brazil.
40. Workshop organized by Murex Diagnostica GmbH. October 12, 1995. Zurich, Switzerland.
41. XVth Asian and Oceanic Congress of Obstetrics and Gynecology. October 15-20, 1995. Bali, Indonesia.
42. Gene Quantification: Diagnosis, Monitoring & Drug Development. February 26-27, 1996. San Diego, California.
43. VIII Curso Internacional de Cancer Cervico Uterino y Lesiones Premalignas. March 7-9, 1996. Mexico City, Mexico.
44. Gene Detection: Diagnostic Technology for Infectious Agents and Human Genetic Diseases. May 2-3, 1996. Coronado, California.
45. 9th World Congress of Cervical Pathology and Colposcopy. May 12-16, 1996. Sydney, Australia.
46. EUROGIN-WHO International Joint Experts Meeting "Cervical Cancer Screening and New Developments. June 17-19, 1996. Geneva, Switzerland.
47. State of Maryland Department of Health and Mental Hygiene Office of Maternal Health and Family Planning. August 9, 1996. Annapolis, MD.
48. Advances in Nucleic Acid Amplification & Detection. September 18-19, 1996. Amsterdam, The Netherlands.
49. IV Simposio Internacional e III Jornada Baiana de Patologia do Trato Genital Inferior e Colposcopia. October 3-6, 1996. Salvador, Brazil.
50. The American Society for Microbiology, New York City Branch, & St. John's University. November 1, 1996. Jamaica, New York.
51. XIII Latin American Microbiology Congress. November 5-9, 1996. Caracas, Venezuela.
52. Workshop on Cervical Cancer Screening Program. November 6-7, 1996. Juquei, SP, Brazil.
53. EUROGIN-WHO 3rd International Congress on Lower Genital Tract Infections and Neoplasia: Future Challenges and Strategies. March 25-28, 1997. Paris, France.
54. 15th Annual Reproductive Health Update, co-sponsored by the Maryland Department of Health and Mental Hygiene Office of Maternal Health and Family Planning, Anne Arundel Community College, and Planned Parenthood. April 25, 1997. Arnold, MD.
55. Symposium on HPV Infection and Cervical Cancer. May 11, 1997. Seoul, Korea.
56. HPV workshop. May 16, 1997. Taipei, Taiwan, R.O.C.
57. XV FIGO World Congress of Gynecology and Obstetrics. August 3-8, 1997. Copenhagen, Denmark.

58. HPV Testing: European Perspectives on Cervical Neoplasia Prevention, Prognosis and Management. November 13-15, 1997. Geneva, Switzerland.
59. European HPV Clinical Summit Meeting. January 29-30, 1998. Vienna, Austria.
60. IV Reunión Nacional de Colposcopia y Patología Cervical. February 19-21, 1998. Guadalajara, Mexico.
61. Gene Quantification: Clinical Applications and Drug Development. March 30-April 1, 1998. San Diego, CA.
62. Biennial Meeting, American Society for Colposcopy and Cervical Pathology. March 30-April 2, 1998. Scottsdale, AZ.
63. ASCP/CAP Spring Meeting. April 4-8, 1998. Los Angeles, CA.
64. 8th European Course on HPV-Associated Pathology. April 22-24, 1998. Munich, Germany.
65. DNA/RNA Diagnostics. May 19-21, 1998. Washington, DC.
66. Microbial-Linked Diseases: Shifting the Pathogenic Paradigm. June 25-26, 1998. San Diego, CA.
67. Human Papillomavirus Infections and Cervical Cancer. July 7-11, 1998. Montreal, Canada.
68. Simposio Internacional sobre HPV: IV Curso de Atualizacao em Patologia do Trato Genital Preparatorio para Concurso de Qualificacao em Colposcopia. September 3-4, 1998. Belo Horizonte, Brazil.
69. III^{er} Congreso Latinoamericano y II^{do} Congreso Paraguayo de Patologia del Tracto Genital Inferior y Colposcopia. September 7-11, 1998. Asuncion, Paraguay.
70. 17th International Papillomavirus Conference. January 9-15, 1999. Charleston, SC.
71. INCGC - Consensus Conference on Cervical Cancer Screening and Management. January 28-31, 1999. Tunis, Tunisia.
72. HPV Summit 1999: New Approaches to the Detection and Elimination of Cervical Cancer. February 8-10, 1999. Chamonix, France.
73. Centers for Disease Control and Prevention and American Cancer Society External Consultants' Meeting: Prevention of Genital HPV Infection and Sequelae. April 13-14, 1999. Atlanta, GA.
74. 11th International Meeting of Gynaecological Oncology. May 8-12, 1999. Budapest, Hungary.
75. 4th Scientific Meeting on Primary and Secondary Prevention of Gynecological Cancer. May 14-16, 1999. Thessaloniki, Greece.
76. 13th Meeting of the International Society for Sexually Transmitted Diseases Research. July 11-14, 1999. Denver, CO.
77. Reproductive Health '99. September 22-25, 1999. New York, NY.
78. 1999 ASCP/CAP Fall Meeting. September 25-30, 1999. New Orleans, LA.
79. 10th World Congress of Cervical Pathology & Colposcopy. November 7-11, 1999. Buenos Aires, Argentina.
80. North American Sexual Health Management Symposium. November 21-23, 1999. New York, NY.
81. Cervical and Breast Cancer in the Next Millenium. December 3-6, 1999. Mexico City, Mexico.
82. XI Encontro de Atualização em Patologia do Trato Genital Inferior e Colposcopia – Cervicop' 2000. March 23-25, 2000. Sao Paulo, Brazil.
83. EUROGIN 2000: Global Challenge of Cervical Cancer Prevention. April 4-9, 2000. Paris, France.
84. ASCP/CAP Spring Meeting. April 9-12, 2000. Boston, MA.
85. Clinical Implications Conference 1: "Role of Human Papillomavirus in Cervical Neoplasia." April 28-29, 2000. Chicago, IL.
86. 26th National Meeting of the Clinical Ligand Assay Society. May 31-June 2, 2000. Boston, MA.
87. Meeting of the Pathological Society of Great Britain and Ireland. July 12-14, 2000. Nottingham, UK.
88. 7th International Meeting of Genital Tract Pathology & Colposcopy. October 25-30, 2000. Belo Horizonte, Brazil.

Attachment C

**INVITED SPEAKER
DEPARTMENTAL SEMINARS**

1. Heidelberg Cancer Research Center, Heidelberg, Germany, November, 1985.
2. Columbia Hospital for Women, Washington, DC, December, 1985, 1986, and 1991.
3. Fred Hutchinson Cancer Research Center, Seattle, Washington, July, 1988.
4. Johns Hopkins Medical Institutions, Baltimore, Maryland, November, 1990.
5. University of New Hampshire, Department of Microbiology, October, 1991.
6. Sharp Memorial Hospital OB/GYN Department, San Diego, California, November 11, 1993.
7. Prodia Laboratory, Jakarta, Indonesia, May 3, 1994.
8. Bio-Check Laboratories Ltd. Pathology, Diagnostic Virus, and Gynecology Departments, Taipei, Taiwan, R.O.C., May 5, 1994.
9. University College Hospital Virology Department, London, United Kingdom, June 16, 1995.
10. John Radcliffe Infirmary Pathology Department, Oxford, United Kingdom, June 17, 1995.
11. National Cancer Hospital Cytology Department, Oslo, Norway, October 10, 1995.
12. Columbia Hospital for Women Pathology Department, Washington, DC, October 24, 1995.
13. Associated Regional University Pathologists (ARUP), Salt Lake City, UT, February 28, 1996.
14. Washington Hospital Center, Transplant Surgery Department, March, 1996.
15. Health Insurance Plan of New York, Jericho, NY, April 24, 1996.
16. Friedrich Schiller University Department of Obstetrics and Gynecology, Jena, Germany, May 8, 1996.
17. Unilab KPT/ Murex Diagnostica GmbH, HPV workshop for gynecologists/venerologists/pathologists/virologists, Budapest, Hungary, May 10, 1996.
18. Long Island Jewish Medical Center Gynecology Department, New York, NY, June 5, 1996.
19. Washington Gynecological Society, Washington, DC, January 8, 1997.
20. Hyundai Medical Center, Seoul, Korea, May 10, 1997.
21. Seoul National University, Seoul, Korea, May 12, 1997.
22. Papanicolaou Institute, Buenos Aires, Argentina, July 14-16, 1997.
23. Doctors' meeting convened by Murex Central Europe, Vienna, Austria, November 17, 1997.
24. One seminar and one grand rounds, for the departments of Gynecologic Oncology, Biochemistry & Molecular Genetics, and Infectious Diseases at the University of Alabama at Birmingham, December 9-10, 1998.
25. Maryland Bioscience Alliance, High Technology Council of Maryland, Rockville, MD, January 21, 1999.
26. University of Rochester Research Symposium on Human Papillomavirus Infections from the Bench to the Bedside, Rochester, NY, April 30, 1999.
27. Women's Health Task Force Meeting, Washington, DC, February 29-March 1, 2000.
28. Maryland Bioscience Alliance Cancer Forum, High Technology Council of Maryland, Rockville, MD, March 22, 2000.
29. Gynecologic Cancer Translational Research Retreat, Chantilly, VA. May 5-6, 2000.
30. 18th Annual Reproductive Health Update for the Maryland Department of Health, Annapolis, MD. May 19, 2000.
31. Georgetown University Department of Pathology, Washington, DC. May 25, 2000.
32. Cleveland Clinic Foundation, Cleveland, OH. June 30, 2000.

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33. University of Medicine and Dentistry of New Jersey, Scotch Plains, NJ. October 13, 2000.

EF09898/60545